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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Northeast Region
Boston District
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D1151B

January 31, 1997

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-4-97W

Michael H. LeBlanc, President and CEO
TECH-MED I.V., Inc.
400 Riverside Street
Portland, Maine 04103

Dear Mr. LeBlanc:

During an inspection of your firm located in Portland, Maine, conducted on January 9 and 13, 1997, our Investigator determined that liquid and gaseous medical oxygen are being transfilled and distributed. Compressed medical gases, including both liquid and gaseous medical oxygen, are drugs as defined by Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

This inspection revealed that the liquid and gaseous medical oxygen being transfilled and distributed by your firm are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the controls used for the manufacture, processing, packing or holding of these products are not in conformance with the Current Good Manufacturing Practice Regulations (GMPs)(Title 21, Code of Federal Regulations (21 CFR), Parts 210 and 211), such as:

1. Failure to adequately test each batch of oxygen for conformance to final specifications for the drug product prior to release. For example, your firm is using a manifold system to fill high pressure cylinders with compressed medical Oxygen, USP, and fails to assay the contents of the cylinders for both identity and strength prior to release.

2. Failure to perform adequate prefill operations on each high pressure cylinder prior to filling. For example, you failed to pull a vacuum on the high pressure cylinders prior to filling on January 6, and 8, 1997.

3. Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing or holding of the batch was accomplished. For example:

   a. None of the steps prior to the filling of the cylinders and during the filling of the cylinders are recorded for liquid oxygen.

   b. There are no records for the steps prior to filling, e.g., venting, valve inspection, proper cylinder color; and during the filling of the cylinders, e.g., heat, pressure, temperature for medical gaseous oxygen.

4. Failure to establish written procedures for liquid medical oxygen designed to assure that the drug product has the identity and strength it purports or is represented to possess. For example, you have no written procedures for testing, filling, labeling, etc. for liquid medical oxygen. Further, your written procedures for medical oxygen gas is incomplete, or not being followed.

5. Failure to establish that the test procedure used to determine the strength and identity of the liquid oxygen will provide test results that are equivalent or superior to the official test procedure. For example, your firm uses a [redacted] to test the incoming VGL of liquid oxygen for strength and identity. You could not provide test results that this instrument is equivalent or superior to the official test procedure.

6. Failure to maintain complete records of the periodic calibration of the oxygen analyzer. For example, there is no record of calibration of the [redacted] on May 31, 1996 when one batch of ten (10) E cylinders and one batch of ten (10) D cylinders were filled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action by FDA without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

We acknowledge receipt of your January 16, 1997, letter addressed to Investigator Arnold Stebbins responding to the FDA-483. The items that you addressed appeared adequate. In your letter you stated that you are working on rewriting the policies and procedures for the handling of LOX and gas cylinders, and at the completion you will send copies to us. Please indicate when this will be completed when you respond to this Warning Letter.

Your reply should be sent to Bruce R. Ota, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Ota at (617) 279-1675 x119.

Sincerely,

James A. Rahto
District Director
New England District Office